Secretary for Health and Family Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Secretary for Health and Family Services based on the July 16, 2009 Pharmacy and Therapeutics Advisory Committee (PTAC) Meetings.

Description of Recommendation	P & T Vote	Final Decisions (s)
High Potency Statins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least simvastatin and EITHER Lipitor® or Crestor® should be preferred. 2. Continue quantity limits on agents in this class based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA via an electronic step edit. 4. For any new chemical entity in the High Potency Statin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 12 For 0 Against	Selected Preferred Agent (s) simvastatin QL Crestor® QL Vytorin™ QL
New Drugs to Market: Sancuso® Place this product non preferred with appropriate quantity limits in the PDL category titled Anti-Emetics: 5-HT3 Antagonists; however allow for its use if the following criteria are met: Sancuso® will be approved if either of the following criteria are met: • Current treatment with chemotherapy to avoid the need for IV antiemetics (both active and new chemotherapy patients); OR, • Trial and failure of ondansetron.	**Passed** 12 For 0 Against	Sancuso® will be non preferred with appropriate quantity limits in the PDL category titled Anti-Emetics: 5-HT3 Antagonists with the following clinical criteria: Sancuso® will be approved if either of the following criteria are met: • Current treatment with chemotherapy to avoid the need for IV antiemetics (both active and new chemotherapy patients); OR, • Trial and failure of ondansetron.

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Antibiotics: Oxazolidinones 1. DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. 2. Place PA criteria around linezolid to prevent over utilization and preserve it as a last line drug. 3. Continue appropriate quantity limits. 4. For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	**Passed** 12 For 0 Against	Selected Preferred Agent (s) Zyvox® CC, QL
Zyvox® Clinical Criteria 1. Diagnoses to approve: • Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing ▪ Enterococcus faecium ▪ Enterococcus faecalis • Methicillin-Resistant Staph Aureus Infections (MRSA) via current culture and sensitivity testing • Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: ▪ Previously documented MRSA infection, ▪ Previous cellulitis caused by documented MRSA, ▪ Skin and soft tissue infection with abscess, ▪ Patient meets BOTH of the following criteria: ▪ Has tried and failed within the past month any of the following antibiotics: • Tetracycline, or • Sulfamethoxazole /trimethoprim, or • Clindamycin, or • Any fluoroquinolone AND	**Passed** 12 For 0 Against	The following clinical criteria will be applied to Zyvox®: 1. Diagnoses to approve: • Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing ▪ Enterococcus faecium ▪ Enterococcus faecalis • Methicillin-Resistant Staph Aureus Infections (MRSA) via current culture and sensitivity testing • Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: ▪ Previously documented MRSA infection, ▪ Previous cellulitis caused by documented MRSA, ▪ Skin and soft tissue infection with abscess, ▪ Patient meets BOTH of the following criteria: ▪ Has tried and failed within the past month any of the following antibiotics: • Tetracycline, or • Sulfamethoxazole /trimethoprim, or • Clindamycin, or • Any fluoroquinolone

▪ Patient presents with any one of the following risk factors: • Health facility stay/visit (current or within the past month) • Surgery in the past month • Participation in team sports (current or past month) • Jail/Prison (current or in past month) • Military (current or in past month) • History of "spider bite" within the past month • Pediatrics enrolled in daycare or school (current or in past month) • Multiple areas of induration • HIV • Permanent indwelling catheters • Percutaneous implanted device • IV drug user • Previously colonized with multi-drug resistant pathogens including MRSA • Diabetic foot ulcer • End stage renal disease; AND 2. Request is **NOT** for more than a 28 day supply (Pass to RPh if days supply exceeds this) **<u>Clinical consideration</u>:** If Zyvox® was initiated in the hospital; approve to complete the course of antibiotic therapy. Number of days of hospital therapy is included in 28-day total therapy.		AND ▪ Patient presents with any one of the following risk factors: • Health facility stay/visit (current or within the past month) • Surgery in the past month • Participation in team sports (current or past month) • Jail/Prison (current or in past month) • Military (current or in past month) • History of "spider bite" within the past month • Pediatrics enrolled in daycare or school (current or in past month) • Multiple areas of induration • HIV • Permanent indwelling catheters • Percutaneous implanted device • IV drug user • Previously colonized with multi-drug resistant pathogens including MRSA • Diabetic foot ulcer • End stage renal disease; AND 2. Request is **NOT** for more than a 28 day supply (Pass to RPh if days supply exceeds this) **<u>Clinical consideration</u>:** If Zyvox® was initiated in the hospital; approve to complete the course of antibiotic therapy. Number of days of hospital therapy is included in 28-day total therapy.

Description of Recommendation	P & T Vote	Final Decisions (s)
Branded Products with Generic Components: The following branded product with generic components should now require prior authorization: Kenalog® Spray	**Passed** 11 For 1 Abstention 0 Against	The following branded product with generic components will now require prior authorization: Kenalog® Spray
New Drugs to Market: Degarelix Acetate® Allow this product to pay unrestricted until the Gonadotropin Releasing Hormone Receptor Antagonists are reviewed for PDL placement.	**Passed** 11 For 0 Against	Degarelix Acetate® will pay unrestricted until the Gonadotropin Releasing Hormone Receptor Antagonists are reviewed for PDL placement.
New Drugs to Market: Afinitor™ Allow this product to pay after the following clinical criteria are met: Afinitor™ (everolimus) will be approved if the patient has a history of either of the following agents within the past 90 days (unless ALL are contraindicated). • sunitinib (Sutent®) • sorafenib (Nexavar®)	**Passed** 11 For 0 Against	Afinitor™ will pay after the following clinical criteria are met: Afinitor™ (everolimus) will be approved if the patient has a history of either of the following agents within the past 90 days (unless ALL are contraindicated). • sunitinib (Sutent®) • sorafenib (Nexavar®)
New Drugs to Market: Lamictal ODT® Based on the Committee's recommendation when this class was reviewed, place this product preferred in the PDL category titled: Anticonvulsants: Second Generation.	**Passed** 6 For 5 Against	Lamictal ODT® will be placed preferred in the PDL category titled: Anticonvulsants: Second Generation.
New Drugs to Market: Acanya™ Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.	**Passed** 11 For 0 Against	Acanya™ will be placed non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.
New Drugs to Market: Aplenzin™ Place this product non preferred in the PDL category titled Antidepressants: New Generation.	**Passed** 11 For 0 Against	Aplenzin™ will be placed non preferred in the PDL category titled Antidepressants: New Generation.
New Drugs to Market: Asacol HD® Place this product non preferred in the PDL category titled 5-ASA Derivatives, Oral Preparations.	**Passed** 11 For 0 Against	Asacol HD® will be placed non preferred in the PDL category titled 5-ASA Derivatives, Oral Preparations.
New Drugs to Market: Besivance™ Place this product non preferred in the PDL category titled Ophthalmic Antibiotics, Quinolones.	**Passed** 11 For 0 Against	Besivance™ will be placed non preferred in the PDL category titled Ophthalmic Antibiotics, Quinolones.

Description of Recommendation	P & T Vote	Final Decisions (s)
New Drugs to Market: Exforge HCT® Place this product preferred in the PDL category titled Angiotensin Receptor Blockers + CCB (DHP) with the following clinical criteria. Exforge HCT® will be approved if the patient has a history of either of the following agents within the past 365 days: • ACE Inhibitor, OR • Exforge®	**Passed** 11 For 0 Against	Exforge HCT® will be placed preferred in the PDL category titled Angiotensin Receptor Blockers + CCB (DHP) with the following clinical criteria: Exforge HCT® will be approved if the patient has a history of either of the following agents within the past 365 days: • ACE Inhibitor, OR • Exforge®
New Drugs to Market: Gelnique™ Place this product non preferred in the PDL category titled Urinary Tract Antispasmodics; however, allow for its use in patients who cannot tolerate/swallow oral medications.	**Passed** 11 For 0 Against	Gelnique™ will be placed non preferred in the PDL category titled Urinary Tract Antispasmodics; however, it will be allowed for patients who cannot tolerate/swallow oral medications.
New Drugs to Market: Lovaza® Place this product preferred in the PDL category titled Lipotropics: Fibric Acid Derivatives with the following clinical criteria. Lovaza® will be approved if the patient has a history of either of the following agents within the past 90 days: • Fibric Acid Derivative, OR • Statin	**Passed** 12 For 0 Against	Lovaza® will be placed preferred in the PDL category titled Lipotropics: Fibric Acid Derivatives with the following clinical criteria: Lovaza® will be approved if the patient has a history of either of the following agents within the past 90 days: • Fibric Acid Derivative, OR • Statin

<table>
<tr><th>Description of Recommendation</th><th>P & T Vote</th><th>Final Decisions (s)</th></tr>
<tr>
<td><u>New Drugs to Market: Nuvigil®</u>
Place this product non preferred with appropriate quantity limits in the PDL category titled Antihyperkinesis Agents with the following criteria:

Nuvigil® (armodafinil) will be approved if both of the following criteria are met:
• One of the following approvable diagnosis (via ICD-9 override):

<table>
<tr><td rowspan="3">Narcolepsy</td><td>347.00</td></tr>
<tr><td>347.01</td></tr>
<tr><td>347.11</td></tr>
<tr><td rowspan="3">Sleep apnea/hypoapnea syndrome</td><td>780.57</td></tr>
<tr><td>780.51</td></tr>
<tr><td>780.53</td></tr>
<tr><td>Shift work sleep disorder</td><td>307.45</td></tr>
</table>

• Trial and failure of Provigil® (modafinil) via a 90 day look back.</td>
<td>Passed
11 For
0 Against</td>
<td>Nuvigil® will be placed non preferred with appropriate quantity limits in the PDL category titled Antihyperkinesis Agents with the following criteria:

Nuvigil® (armodafinil) will be approved if both of the following criteria are met:
• One of the following approvable diagnosis (via ICD-9 override):

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<td><u>New Drugs to Market: Ryzolt™</u>
Place this product non preferred in the PDL category titled Non-Narcotics.</td>
<td>Passed
11 For
0 Against</td>
<td>Ryzolt™ will be placed non preferred in the PDL category titled Non-Narcotics.</td>
</tr>
<tr>
<td><u>New Drugs to Market: Savella™</u>
Place this product preferred in the PDL category titled Antidepressants: SNRIs, and allow for its use in fibromyalgia only via an ICD-9 Override.</td>
<td>Passed
12 For
0 Against</td>
<td>Savella™ will be placed preferred in the PDL category titled Antidepressants: SNRIs, however, it will be allowed for use in fibromyalgia only via an ICD-9 Override.</td>
</tr>
<tr>
<td><u>New Drugs to Market: Simponi®</u>
Place this product non preferred in the PDL category titled Immunomodulators with quantity limits based on the FDA-approved maximum dose and clinical criteria similar to the other Immunomodulators.</td>
<td>Passed
11 For
0 Against</td>
<td>Simponi® will be placed non preferred in the PDL category titled Immunomodulators with quantity limits based on the FDA-approved maximum dose and clinical criteria similar to the other Immunomodulators.</td>
</tr>
<tr>
<td><u>New Drugs to Market: Zinotic ES®</u>
Place this product non preferred in the PDL category titled Otic: Miscellaneous.</td>
<td>Passed
11 For
0 Against</td>
<td>Zinotic ES® will be placed non preferred in the PDL category titled Otic: Miscellaneous.</td>
</tr>
</table>

Description of Recommendation	P & T Vote	Final Decisions (s)
Penicillins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, ampicillin, dicloxacillin and penicillin V should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) amoxicillin ampicillin dicloxacillin penicillin V
Penicillin/Beta-Lactamase Inhibitor Combinations 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin/clavulanate should be preferred on the PDL. 2. If amoxicillin/clavulanate ES is selected as non preferred allow for its use in patients less than 12 years of age. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Penicillin/Beta-Lactamase Inhibitor Combination class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) amoxicillin/clavulanate amoxicillin/clavulanate ES-600
First Generation Cephalosporins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) cephalexin cefadroxil

Description of Recommendation	P & T Vote	Final Decisions (s)
Second Generation Cephalosporins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) cefaclor cefprozil cefuroxime
Third Generation Cephalosporins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) cefdinir cefpodoxime Spectracef® Suprax®
Ketolides 1. DMS to select preferred agent(s) based on economic evaluation. 2. Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only. 3. Continue current quantity limit (10 days supply per month). 4. For any new chemical entity in the Ketolide class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) Ketek® CC

Description of Recommendation	P & T Vote	Final Decisions (s)
Ketek® Clinical Criteria 1. Diagnosis of Community Acquired Pneumonia (CAP) OR Acute Exacerbation of Chronic Bronchitis AND 2. Must have previously used (within the past 28 days) ONE of the following: a. Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam) b. 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone) c. Macrolide (e.g., azithromycin, clarithromycin, erythromycin) d. Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) e. Tetracycline (e.g., doxycycline) f. Trimethoprim/sulfamethoxazole (e.g., Bactrim) AND 3. Request is not for more than a 10 day supply. **Clinical Consideration** If Ketek™ was initiated in the hospital; approve to complete the course of antibiotic therapy.	**Passed** 10 For 1 Abstention 0 Against	The following clinical criteria will be applied to Ketek®: 1. Diagnosis of Community Acquired Pneumonia (CAP) OR Acute Exacerbation of Chronic Bronchitis AND 2. Must have previously used (within the past 28 days) ONE of the following: a. Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam) b. 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone) c. Macrolide (e.g., azithromycin, clarithromycin, erythromycin) d. Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) e. Tetracycline (e.g., doxycycline) f. Trimethoprim/sulfamethoxazole (e.g., Bactrim) AND 3. Request is not for more than a 10 day supply. **Clinical Consideration** If Ketek™ was initiated in the hospital; approve to complete the course of antibiotic therapy.
Tetracyclines 1. DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred. 2. If demeclocycline is selected as non preferred, allow for its use in SIADH only via an ICD-9 override. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 1 Abstention 0 Against	Selected Preferred Agent (s) demeclocycline doxycycline minocycline tetracycline

Description of Recommendation	P & T Vote	Final Decisions (s)
Sulfonamides, Folate Antagonist 1. DMS to select preferred agent (s) based on economic evaluation; however, at least trimethoprim/sulfamethoxazole should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Sulfonamides, Folate Antagonist class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 1 Abstention 0 Against	Selected Preferred Agent (s) sulfadiazine trimethoprim trimethoprim/sulfamethoxazole
Oral Antifungals 1. DMS to select preferred agent(s) based on economic evaluation; however, all currently available unique chemical entities should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Remove prior authorization requirements from terbinafine; however, continue prior authorization requirements for itraconazole. 4. For any new chemical entity in the Oral Antifungal class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) clotrimazole fluconazole griseofulvin itraconazole CC ketaconazole nystatin terbinafine Ancobon® Gris-Peg® Noxafil® Vfend®

Itraconazole Clinical Criteria
Diagnoses to approve:
• Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot):
  • If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, refer the request to a clinical pharmacist.
  • If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy.
• Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks
• Onychomycosis (fungal infection of the
	Passed
	11 For
	0 Against
		The following clinical criteria will be applied to itraconazole:
		Diagnoses to approve:
		• Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot):
		  • If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, refer the request to a clinical pharmacist.
		  • If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy.
		• Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks

fingernails or toenails):
• Approval is based on initial vs. continuation or retreatment as follows:
  • For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO
  • For retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment:
• Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy.
• Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy.
• For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.
		• Onychomycosis (fungal infection of the fingernails or toenails):
		  • Approval is based on initial vs. continuation or retreatment as follows:
		  • For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO
		  • For retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment:
		  • Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy.
		  • Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy.
		• For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.

<u>Antivirals: Herpes</u> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Antivirals, Herpes class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 11 For 0 Against	<u>Selected Preferred Agent (s)</u> acyclovir Valtrex®

Description of Recommendation	P & T Vote	Final Decisions (s)
Antivirals: Influenza 1. DMS to select preferred agent (s) based on economic evaluation; however, at least amantadine, oseltamivir, rimantadine and zanamivir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Secretary approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review. 4. For any new chemical entity in the Antivirals, Influenza class, require a PA until reviewed by the P&T Advisory Committee, unless recommended to be preferred per #3 above.	**Passed** 11 For 0 Against	Selected Preferred Agent (s) amantadine rimantadine Tamiflu® Relenza®